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May 19, 2003

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Art Unit 1644

Re: U.S. Utility Patent Application
Appl. No. 09/832,922; Filed: April 12, 2001
For: **Compositions and Methods for Use in Modulating Immune System Function**
Inventors: Geissmann *et al.*
Our Ref: 1383.0260001/EKS/BJD

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Reply to Restriction Requirement and Requirement for Election of Species; and
2. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

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BJD:nef
Enclosures

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:
GEISSMANN *et al.*
Appl. No. 09/832,922
Filed: April 12, 2001
For: **Compositions and Methods for Use in Modulating Immune System Function**

Confirmation No.: 8471
Art Unit: 1644
Examiner: Huynh, P.N.
Atty. Docket: 1383.0260001/EKS/BJD

Reply To Restriction Requirement and Requirement for Election of Species

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to the communication dated May 1, 2003 (Paper No. 6), Notice of Non-Compliant Response, Applicants reply as follows. Applicants apologize for the inadvertent oversight in not including an election of species in the reply filed in the present matter on May 22, 2002 (a courtesy copy of which was re-submitted to the Office on December 6, 2002).

The provisional election of restriction Group I, represented by claims 1-2, 4-5, 10 and 16, which election was made in Applicants' original reply, is affirmed. In reply to the requirement for election of a single species of cytokine from those disclosed on page 72 of the specification, Applicants provisionally elect tumor necrosis factor alpha (TNF-α). These elections are made without prejudice to or disclaimer of the other claims or inventions disclosed.

These elections are made **with** traverse. The criteria for a proper requirement for restriction are that (1) the inventions must be independent or distinct as claimed; and (2) there must be a serious burden on the Examiner if restriction is not required. MPEP § 803. Neither

of these criteria has been met; therefore, Applicants respectfully assert that the present restriction requirement is in error. Reconsideration and withdrawal are respectfully requested.

As an initial matter, Applicants respectfully assert that the claims in Groups I-XLVI are closely related in subject matter. As such, a search of one group of claims is likely to encompass subject matter pertinent to the patentability of all groups, particularly since all of the groups have been classified by the Examiner in class 424, subclass 198.1. Moreover, the Examiner has provided no reasoning as to why, for example, claims 1-2, 4-6, 10 and 16 are each restricted into numerous separate restriction groups (*e.g.*, Groups I and II *both* contain *only* claims 1, 2, 4, 5, 10 and 16, and Groups III-V *all* contain *only* claims 1-2, 4, 6, 10 and 16; this pattern is repeated for numerous other sets of claims throughout the restriction requirement). Indeed, Applicants note that although the present application contains only 37 claims, these claims have been restricted into *46 separate restriction groups* (*see* Paper No. 2 at pages 2-10). The basis of restriction practice is the statutory requirement under 35 U.S.C. § 101 that a patent application be drawn only to one independent and distinct invention. Applicants respectfully submit that restricting the present application into more restriction groups than there are claims pending in the application is improper under the statutes, rules and guidelines for proper restriction. Instead, the Examiner's grouping of claims would seem more appropriate for an Election of Species requirement under MPEP § 809.02(a) (although Applicants respectfully assert that such a requirement would also be improper). Hence, the first requirement for proper restriction -- that the alleged inventions be independent and distinct as claimed -- is not met in the present case.

Similarly, the Examiner has not satisfied the second requirement set forth in MPEP § 803, *i.e.* the Examiner has not shown why a serious burden would be imposed on the Examiner if restriction were not required. The Examiner has not shown by appropriate explanation any of

the three reasons supporting a serious burden if restriction were not required, as set forth in MPEP § 808.02. Moreover, as noted above, all of the groups have been classified by the Examiner into class 424, subclass 198.1. By definition, then, a search of only this one class and subclass should uncover art relevant to every one of the listed restriction groups. A serious burden therefore has not been established, and "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." MPEP § 803.

Thus, neither of the criteria for establishing a proper restriction requirement has been established in the present case. It should be noted that the two requirements set forth in MPEP § 803 are connected with "and;" satisfaction of both criteria therefore is required. Hence, Applicants respectfully assert that for at least these reasons, the present restriction requirement is improper; reconsideration and withdrawal, and consideration of all pending claims, are therefore respectfully requested.

Applicants also respectfully traverse the requirement for election of species. In making this requirement, the Examiner contends that "[t]hese cytokines differ with respect to their structure and activity. Therefore they are patentably distinct." Paper No. 2 at page 11, section 6, lines 4-5. Applicants respectfully disagree. The point of novelty of the presently claimed methods and compositions is not the specific cytokine that is used. Instead, the primary point of novelty is the *combination* of retinoid and cytokine chosen for use in these methods and compositions. Hence, whether or not the cytokines encompassed or recited by the present claims are "patentably distinct" is irrelevant for examination purposes. This is particularly so since, as noted above, a search of one restriction group (including claims reciting or encompassing a variety of cytokines) is likely to uncover art relevant to the patentability of all of the other groups.

Accordingly, the Examiner has not demonstrated that it would be unduly extensive and burdensome to search species encompassed and/or recited by the present claims. For at least these reasons, the present requirement for election of species is improper; reconsideration and withdrawal of this requirement therefore are respectfully requested.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Brian J. Del Buono
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Registration No. 42,473

Date: May 19, 2003

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